REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated December 24, 2003 are respectfully requested.

I. Rejections under 35 C.F.R. §103

Claims 1, 5-7, 9-12, 14, 22-25, 28-29, 31-32, 34, 42-44, 49, 50, 79, and 80 were rejected under 35 U.S.C. §103 as allegedly obvious over Gough *et al.* (U.S. Patent No. 5,735,847) in view of Benaron *et al.* (U.S. Patent No. 5,762,609, hereinafter the '609 patent) and further in view of Benaron *et al.* (U.S. Patent No. 5,769,791, hereinafter the '791 patent).

Claims 45-48 were rejected under 35 U.S.C. §103 as allegedly obvious over Gough *et al.* in view the '609 patent and further in view of the '791 patent and further in view of Hoey *et al.* (U.S. Patent No. 6,409,722).

Claims 52-74 were rejected under 35 U.S.C. §103 as allegedly obvious over Gough *et al.* in view the '609 patent and further in view of the '791 patent and further in view of Ben-Haim *et al.* (U.S. Patent No. 6,200,310).

These rejections are respectfully traversed.

A. The Present Invention

The present invention, as embodied by claim 1, describes a tissue biopsy and treatment apparatus for detecting and treating tumors. The apparatus comprises (i) an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue, (ii) a sensor array deployable from the elongated delivery device, and (iii) an optical switching device to switch a mode of said optical sensor. The sensor array includes a plurality of resilient members each having a tissue piercing distal portion. Additionally, the sensor array has a geometric configuration adapted to volumetrically sample tissue at a tissue site or identify tissue at a tissue site. Moreover, the sensor array is configured to measure a spectral profile of at least one portion of the tissue site. At least one of the plurality of resilient members is positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery

device in a deployed state. In addition, at least one of the plurality of resilient members includes an optical sensor operatively connected to function as an emitter and a detector. Further, at least some of the resilient members are electrodes which can be coupled to an RF energy source for ablating tissue when electrical energy is supplied to the electrodes from the source.

In the embodiment described in claim 14, the sensor array has a geometric configuration adapted to volumetrically sample and measure a spectral profile of at least one portion of a tissue site to differentiate or identify tissue at the tissue site.

Claim 42 describes an embodiment including at least a first and a second sensor selected from an emitter, an electromagnetic emitter, an optical emitter, an acoustical emitter, a laser, and an LED.

In the embodiment described in claim 52, the apparatus is additionally configured to detect a marking agent.

B. The Prior Art

GOUGH ET AL. describe a multiple antenna ablation device. The multiple antenna device includes a primary antenna with a lumen and a longitudinal axis and a distal end sufficiently sharp to pierce tissue, and a secondary antenna at least partially positioned in the secondary antenna. The secondary antenna includes a distal portion configured to be deployed from the lumen in a lateral direction relative to the longitudinal axis, wherein at least a part of a deployed secondary antenna distal portion has at least one radius of curvature. The device is configured to be coupled to an energy source. The device further includes a cooling element coupled to the primary antenna.

BENARON ET AL., THE '609 PATENT relate to a device and method for detecting chemical or histological changes over time in a tissue. The device may include more than one probe to irradiate the tissue and detect the emitted radiation. The device includes an emitter and a detector or an emitter and multiple detectors. The emitter may be an ambient light source, an infrared light source, a laser beam, a light emitting diode, a fluorophore, a radio emitter, a radio wave source, or a self-emitting source.

BENARON ET AL., THE '791 patent relate to an instrument to interrogate tissue non-destructively for surgical procedures. The instrument includes a probe member and a plurality of optical components disposed on the member. The optical components include one or more optical emitting windows through which light emitted by a light source is launched to illuminate tissue and one or more optical detecting windows. The instrument preferably includes one or more optical emitting windows on one member and one or more optical detecting windows facing a tissue contacting surface of the other member (Col. 5, lines 63-66). In a single member tip, the light source and detector may be mounted side by side on a planar surface (Col. 16, lines 52-54). In one embodiment, the optical components are optical fibers that are plugged into a coupler that is keyed so that a selected optical fiber may be used for sensing or illuminating, but not both (Col. 22, lines 49-52). The '791 patent further describes a coupler which multiplexes and transmits multiple wavelengths emitted by several sources. One optical channel is configured as a transmission channel and another channel is configured as the reception channel (Col. 25, lines 16-20).

HOEY ET AL. relate to an apparatus and a method for producing a virtual electrode within or upon a tissue to be treated with radio frequency alternating electric current. The apparatus includes a supply of a conductive or electrolytic fluid to be provided to the patient, an alternative current generator, and a processor for creating, maintaining and controlling the ablation process by the interstitial or surficial delivery of the fluid to a tissue and the delivery of electric power to the tissue via the virtual electrode. The method in accordance with the invention includes the steps of delivering a conductive fluid to a predetermined tissue ablation site for a predetermined time period, applying a predetermined power level of radio frequency current to the tissue, monitoring at least one of several parameters and adjusting either the applied power and/or the fluid flow in response to the measured parameters.

BEN-HAIM ET AL. relate to an apparatus for percutaneous myocardial revascularization for creating channels in ischemic heart tissue using laser, RF,

ultrasound, and mechanical methods. The apparatus may include a sensor for receiving signals generated by the body of the subject responsive to the treatment. In one embodiment, the sensor is an optical sensor which receives light emitted by endocardial tissue.

C. Analysis

1. Legal Standard

According to the MPEP § 2143, "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations."

2. Rejection over Gough *et al.* in view of the '609 patent and further in view of the '791 patent

The combination of Gough *et al.* and the '609 patent, was discussed in Applicant's response of October 14, 2003. Briefly, both of the references, alone or in combination, fail to teach (a) an apparatus where at least one of the plurality of resilient members includes an optical sensor operatively connected to function as an emitter and a detector, and (b) a switching device for switching the mode of the optical sensor. Gough *et al.* makes no mention of an optical sensor functioning as either an emitter or a receptor. The '609 patent teaches an apparatus using an emitter and a separate receptor. Further, neither of the references make any mention of a switching device for switching the mode of the optical sensor.

Addition of the '791 patent does not alter this analysis as the '791 patent also fails to teach (a) an apparatus where at least one of the plurality of resilient members includes an optical sensor operatively connected to function as an emitter and a detector, and (b) a switching device for switching the mode of the optical sensor. As

seen in Fig. 4A, the '791 patent teaches an apparatus using a separate transmission (45) channel and reception channel (46) as well as a separate light source (43) and light detector (47).

The Examiner cites elements 995, 43, and 947 disclosed in Fig. 9 as a teaching of an optical sensor connected to function as an emitter and a detector. However, a careful reading of the '791 patent shows that the optic module (995) cannot be relied upon for a teaching of an optical sensor connected to function as an emitter and a detector. As seen in Fig. 9, the coupler (995) is an optics module that transmits and receives monochromatic light over optic fibers at different wavelengths (Col. 25, lines 8-12). Light from different light sources (43-1, 43-2, and 43-3) is transmitted through a transmission channel (992) to a first optic fiber (945) and into the tissue. A second optic fiber (946) passes detected light from the tissue to a reception channel (993), which is separate from the transmission channel, to the photo detector (947).

The '791 patent further fails to teach a switching device for switching the mode of the optical sensor. The apparatus of the '791 patent includes a coupler (994) that provides synchronous multiplexing of the multiple light sources such that only one light source is illuminated at a time according to a selected sequence (Col. 25, lines 42-56). Thus, the coupler (994) of the '791 patent multiplexes wavelengths from different light sources, not switches the optical sensor mode as presently claimed.

3. Rejection over Gough *et al.* in view of the '609 patent and further in view of the '791 patent and further in view of Hoey *et al.*

According to M.P.E.P. §2143.03, if an independent claim is non-obvious under 35 U.S.C. then any claim depending therefrom is non-obvious. The rejection of dependent claims 45-48 relies on Gough *et al.* in view of the '609 patent and further in view of the '791 patent, the deficiencies of which are discussed above. The teaching in Hoey *et al.* is cited merely for the inclusion of baseline impedance measurements. The teaching in Hoey *et al.* does not make up for the deficiencies in Gough *et al.*, the '609 patent, and the '791 patent, as this reference makes no mention of an optical sensor operatively connected to function as an emitter and a detector or of a switching device.

4. Rejection over Gough *et al.* in view of the '609 patent and further in view of the '791 patent and further in view of Ben-Haim *et al.*

As described above, the ablation device of claim 52 includes (i) an elongated delivery device, (ii) a sensor array deployable from the elongated delivery device, and (iii) an optical switching device. The sensor array includes a plurality of resilient members each having a tissue piercing distal portion. At least one of the plurality of resilient members includes an optical sensor operatively connected to function as an emitter and a detector.

As described above, Gough *et al.*, the '609 patent, and the '791 patent, alone or in combination, fail to teach either element (i), an optical switching device, or an apparatus where at least one of the plurality of resilient members includes an optical sensor operatively connected to function as an emitter and a detector. None of Gough *et al.*, the '609 patent, or the '791 patent make any mention of an optical switching device as presently claimed. Additionally, none of the references teach an optical sensor operatively connected to function as an emitter and a detector. Gough *et al.* makes no mention of an optical sensor functioning as either an emitter or a receptor. The '609 and '791 patents each teach an apparatus having an emitter and a separate receptor.

The Ben-Haim *et al.* reference is cited merely for the inclusion of sensors that detect fluorescent markers. The teaching in Ben-Haim *et al.* does not make up for the deficiencies in Gough *et al.*, the '609 patent, and the '791 patent, as Ben-Haim *et al.* make no mention of either an optical sensor operatively connected to function as an emitter and a detector or of a switching device.

Because the references fail to teach all the claim limitations of the present invention, the standard for obviousness has not been met. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for Allowance. A Notice of Allowance is therefore respectfully requested.

The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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Date: March 24, 2004

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